

23. (Twice Amended) An endoscopic system comprising an endoscopic instrument, said endoscopic instrument comprising:

a shaft,
a handle arranged at a proximal end of said shaft,
at least one working part arranged at a distal end of said shaft, and
at least one fluorescent marking, having a fluorescing substance that can be excited to fluoresce by a light source, said marking is provided at a distal end section of said endoscopic instrument,

wherein said fluorescing substance is selected in such a way that its excitation range lies in an excitation range of a tissue-autofluorescence,

said light source is selected in a way that it only emits light of specific wavelength ranges matching excitation ranges of both said fluorescent marking of said instrument and said tissue auto-fluorescence, therefore said same light source can excite both fluorescence phenomena.

REMARKS

Regarding priority, Applicant respectfully informs the Examiner that a certified copy of the foreign priority document was filed on November 6, 2001. Attached hereto is a copy of documents evidencing such filing. Applicant asks the Examiner to please check the file again, as perhaps the foreign priority document was overlooked.

All claims stand rejected under 35 U.S.C. §103(a) as being unpatentable over Iacovelli (U.S. Patent No. 5,350,391) in view of Gain (U.S. Patent No. 3,840,015) and in some cases further in view of various tertiary references. This rejection is respectfully traversed.

As an initial matter, Applicant would like to clarify several terms used by the Examiner, specifically the terms "visible light," "white light" and "visible white light."

The term "visible light" describes any light with any frequency spectrum as long as it is detectable by the human eye. The frequency spectrum hereby might be very broad or very narrow. Visible light can indeed be monochromatic.

The term "white light," on the other hand, is light that contains a very broad frequency spectrum, containing virtually all wavelengths in the visible spectrum. Thereby it is perceived by the human eye as being white. White light as obtained from light sources such as commercially available light bulbs, does even contain light outside the spectrum detectable by the human eye such as IR or UV light. "White radiation" in general usually denominates radiation which covers a broad frequency spectrum of any given type of radiation.

Visible white light can therefore be understood to describe radiation (light) that covers the whole frequency spectrum of visible light.

The nucleus of the invention is the fact that the conditions are set in way that operations are performed under a light source with a relatively narrow frequency spectrum. The relatively low intensity fluorescence emissions by the fluorescent material applied to the instrument, the tumor-specific photosensitizer or the auto-fluorescence of malignant tissue are therefore not drowned out by emissions from the external light source.

Independent claims 1 and 23 have been amended to further highlight this novel feature of the invention, which is disclosed on pages 7 and 19 of the present application.

On page 2, lines 20 to 23, and on page 3, lines 2 to 10 of the Office Action, the Examiner remarks that Gain teaches to use a photoluminescent material such as eosin, fluorescein or rhodamine and that Gain teaches that the fluorescing substance is selected in such a way that the excitation range lies in the excitation range of the tumor-specific photosensitizer or in the excitation range of a tissue

auto-fluorescence. This is in fact not the case as can be seen from column 2, line 14 to line 16 of Gain, which states:

"The particular photoluminescent substance to be employed is not highly critical, the principal criteria for the selection thereof being that it is substantially non-toxic."

Gain discloses to use any photoluminescent material, as long as it is not toxic, and to select a light source suitable to stimulate luminescence.

Gain does not disclose to stimulate simultaneously the luminescence of both an instrument and a luminescent tissue.

On page 5, line 6 to 9 of the Office Action, the Examiner expresses her disagreement with the fact that Iacovelli cannot perform surgery using a white light source to establish the fluorescence phenomenon.

Although white light contains light in the excitation frequency range of tissue-specific photosensitizers or auto-fluorescence in this case, one has to remember that white light also contains light in the emission range. Due to the nature of the fluorescence phenomenon, the level of emitted radiation will always be significantly lower than the level of radiation needed for the excitation process. If a light source with a broad frequency range is used for the excitation process

(such as white light) as disclosed by Iacovelli, the information carrying emission signal would be drowned out, similar to a phenomenon when so-called white noise, such as running water, drowns out a signal carrying sound, such as a conversation.

Although Iacovelli can actually use a white light source to establish a fluorescence phenomenon, the use of such a non specific light source will lead to the fluorescence emission being no longer observable, especially in the case of tissue auto-fluorescence and the fluorescence of a tissue-specific photosensitizer.

On page 8, line 14 to page 9, line 6 of the Office Action, the Examiner argues that Gain teaches to use fluorescent substances with an excitation range of 400 to 500 nanometers in order to improve the visibility of surgical instruments. The fluorescence phenomenon is hereby used to delineate surgical instruments against the background that does not show fluorescence. The same effect would be achieved if one was to apply Gain's teaching to endoscopic surgical instruments as described by Iacovelli.

In both cases the conditions are set in a way that even without the fluorescent markings the instruments as well as the tissue would be clearly visible to the human eye. If these conditions were applied to the problems as described

in the present invention it would not be possible to obtain all the desired information, here the presence and extent of malignant tissue.

The teachings of Iacovelli and Gain use fluorescence to create a contrast between the background tissue and the surgical instrument. This runs almost contrary to the present invention. If a maximum of contrast is desired as it is the case for Iacovelli and Gain the luminescent markings would be chosen in a way not to coincide with other fluorescence phenomena.

The aim of the invention is to make particular parts of the tissue and the surgical instruments visible at the same time and under the same conditions. This allows the surgeon to bring the luminescing instrument close to the luminescing part of the tissue in order to perform a surgery, for example a biopsy of that luminescing part of the tissue.

This is particularly notable if the excitation frequency used is outside the frequency range detectable by the human eye, where the observer is given the impression that the only illumination is provided by the fluorescence of the malignant tissue, or the tumor-specific photosensitizer and the fluorescent markings on the surgical instrument.

A similar effect can be achieved if excitation light within a frequency band visible to the human eye is used, but the excitation light is then in turn kept away from the observer through the use of, for example, optical filters.

Again in this case white light cannot be employed, because the white light does contain light of the same frequency as emitted by the fluorescent material present which would then in turn make the observation of any fluorescence phenomenon impossible

For the foregoing reasons, Applicant respectfully submits that all pending claims, namely Claims 1-44, are patentable over the references of record, and earnestly solicits allowance of the same.

Respectfully submitted,



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